OCT 2 0 2005 K052581

Special 510(k) Premarket Notification
GE Medical Systems Lunar – Lunar iDXA Bone Densitometer
September 19th, 2005

Attachment B

510 (k) Summary of Safety and Effectiveness

Prepared in accordance with 21 CFR Part 807.92(c).

GE Healthcare

Section a):

1. Submitter: GE Medical Systems Ultrasound and Primary Care Diagnostics, LLC division of General Electric Company
GE Medical Systems Lunar (business name)
726 Heartland Trail
Madison, WI 53717

Contact Person: James P. Raskob
Safety and Regulatory Engineering Manager
Telephone: 608-826-7425; Fax: 608-299-2132

Date Prepared: September 19th, 2005

2. Device Name: Lunar iDXA bone densitometer Bone Densitometer, 21 CFR 892.1170, 90-KGI

3. Marketed Device: Prodigy bone densitometer: K915535 K982267 K983564 K000826 K001756 K001812 K011917 K023554 currently in commercial distribution.

4. Device Description: The Lunar iDXA bone densitometer is a full featured general purpose x-ray bone densitometer system. It consists of a scan table that provides x-ray source generation, digital x-ray detection and processing. The user interface includes a computer workstation and a color monitor display. This modification will provide users with improved image resolution and ease of use with patients of larger size.

5. Indications for Use: The Lunar iDXA Bone Densitometer provides an estimate of bone mineral density and fat and lean tissue mass. The values can then be compared to a reference population at the sole discretion of the physician.

6. Comparison with Predicate Device: The Lunar iDXA is of a comparable type and substantially equivalent to the current Prodigy bone densitometer. It has the same technological characteristics, is comparable in key safety and effectiveness features, it utilizes similar design, construction, and materials, and has the same intended uses and basic operating modes as the predicate device.

Section b):

1. Non-clinical Tests: The device has been evaluated for electrical and mechanical safety, and has been found to conform with applicable medical device safety standards. In vitro precision and accuracy values were computed through a series of tests on phantoms and were within design specifications.

2. Clinical Tests: No clinical tests were required to establish safety or effectiveness, however a 40 person in vivo study was done to verify that the design specifications of accuracy and precision were met.

3. Conclusion: Intended uses and other key features are consistent with previously cleared bone densitometer. The design and development process of the manufacturer conforms with 21 CFR 820 and ISO 13485 quality systems. The device conforms to applicable medical device safety standards and compliance was verified through independent evaluation with ongoing factory surveillance. The Lunar iDXA bone densitometer is substantially equivalent to currently marketed devices. No new safety and effectiveness questions are raised with the Lunar iDXA bone densitometer.

Attachment C
Truthful and Accurate Statement

PREMARKET NOTIFICATION TRUTHFUL AND ACCURATE STATEMENT
(as required by 21 CFR 807.87(j))

I certify that, in my capacity as of Safety and Regulatory Engineering Manager for GE Medical Systems Lunar, I believe, to the best of my knowledge, that all data and information submitted in this premarket notification are truthful and accurate and that no material fact has been omitted.

James P. Raskob Date: Sept 19th, 2005

James P. Raskob

510(k) number: _____

* Must be signed by a responsible person of the firm required to submit the premarket notification (e.g., not a consultant for the 510(k) submitter).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 0 2005

Mr. James P. Raskob
Safety & Regulatory Engineering Manager
GE Medical Systems Lunar
GE Healthcare
726 Heartland Trail
MADISON WI 53717

Re.: K052581
Trade/Device Name: Lunar iDXA
Regulation Number: 21 CFR 892.1170
Regulation Name: Bone Densitometer
Regulatory Class: II
Product Code: KGI
Dated: September 19, 2005
Received: September 20, 2005

Dear Mr. Raskob:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K052581

Device Name: Lunar iDXA

Indications For Use:
The Lunar iDXA Bone Densitometer provides an estimate of bone mineral density and fat and lean tissue mass. The values can then be compared to a reference population at the sole discretion of the physician.

Prescription Use ___X___ ~~AND~~/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David B. Lyerly

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K052581